REMARKS

In the most recently received (final)l Official Action, the Examiners have rejected pending claims 11-15 respectively under 35 U.S.C. 112, second paragraph, as being indefinite in language. In addition, the Examiners have rejected pending claims 11-15 under 35 U.S.C. 102(b) as being inherently anticipated by the Blecha *et al.* publication (WO 96-32129).

In response, applicants have amended pending independent claims 11 and 15 respectively; and again present pending dependent claims 12-14 respectively for review. By these claim amendments and the discussion presented hereinafter, applicants believe they have overcome and obviated each basis for rejection stated by the Examiners in the instant Official Action.

I. Applicants' Claimed Invention

Applicants' invention is claimed specifically as a "PR-39 derived oligopeptide family". This term, "PR-39 derived oligopeptide family", is defined by amended independent claims 11 and 15 respectively as a combination of requisite elements and particular limitations; and comprises a family whose individual members cause a selective inhibition of protease-mediated degradation in-situ after introduction intracellularly to a viable cell. In addition, several preferred embodiments of the membership constituting

the PR-39 derived oligopeptide family are defined by dependent claims 12, 13 and 14 respectively as precisely recited amino acid residue sequences of differing lengths.

In particular, it will be noted and appreciated that the wording of presently amended independent claims 11 and 15 are broader definitions which encompass the commonly shared characteristics and properties of the 15, 11, and 8 amino acid residue length structures; and delineate a circumscribed membership which is size-limited, is functionally specific, and is structurally related as a family of shorter-length, pharmacologically active oligopeptides which are structurally analogous to the amino acid residue sequence to be found at the N-terminal end of the native PR-39 molecule.

In addition, the commonly shared characteristics and properties of the PR-39 derived oligopeptide family are overtly restated and individually set forth as the requisite elements and specific limitations recited by amended independent claims 11 and 15 respectively. Thus, amended independent claim 11 (or claim 15) requires that each PR-39 derived oligopeptide family member present not less than six separate and individual traits and attributes. These are:

(1) a peptide which is pharmacologically active and is less than 26 (or 20) amino acid residues in length;

(2) a peptide whose N-terminal amino acid residue sequence begins with Arg-Arg-Arg;

(3) a peptide which is an analog of the amino acid sequence of native PR-39 peptide;

(4) a peptide which selectively alters the proteolytic degradation activity of proteasomes in-situ;

(5) a peptide able to interact in-situ with at least the α7 subunit of such proteasomes as are present within the cytoplasm of the cell; and

(6) a peptide able selectively to alter the proteolytic degradation activity of said proteasomes having an interacting α7 subunit such that the proteolytic degradation mediated by said proteasomes against at least one peptide selected from the group consisting of IκBα and HIF-1α becomes inhibited without substantially altering other proteolytic degradation mediated by said proteasomes.

It will be noted and understood by the Examiners that amended independent claims 11 and 15 respectively set forth a precise recitation of the requisite elements and limitations comprising the minimal component parts of applicants' inventive subject matter as a whole; and that the entirety of the claim language as recited - rather than any fraction or portion - constitutes and specifies the requisite elements and particular limitations of applicants' claimed invention.

II. The Rejection Under 35 U.S.C. 112, 2nd Paragraph

The Examiners have rejected the original claims under 35 U.S.C. 112, 2nd paragraph as being vague and indefinite in language. The Examiners' position is based on the use of the phrase "a specific peptide" in different parts of the claims. In response, applicants direct the Examiners' attention to the deletion of this phrase from the claim language; and to the other multiple, substantive changes in the wording of independent claims 11 and 15 as presently amended.

Accordingly, as regards the language of the pending claims as a whole, the essential inquiry is to determine whether the language of the pending claims do, in fact, set out and circumscribe a particular area or subject matter with a reasonable degree of precision and particularity. It is here where the meaning of the words and language employed to define the invention is analyzed; not in a vacuum, but always with regard to the teachings of the prior art and within the particular description, use or context disclosed by the Specification as it is understood and interpreted by one possessing ordinary skill in the pertinent art [In re Angstadt, 190 USPQ 214 (CCPA 1976)].

Finally, applicants note that each of the terms used in pending claims respectively is well understood; is not subject to numerous definitions and interpretations; and that there is no discrepancy, no confusion, and no

ambiguity with regard to the antecedent descriptive basis and support provided by the Specification text. Rather, the language of the presently pending claims as a whole read on subject matter which is completely disclosed and enabled by the Specification text. Moreover, each recited element of the pending claims is explicit and clearly stated; and employs wording which sets forth and circumscribes the particular subject matter area with the requisite reasonable degree of precision and particularity [In re Moore, 169 USPQ 236 (CCPA 1971)].

For these reasons, applicants respectfully submit that each and every claim now pending satisfies the requirements of precision, clarity, and particularity required by the second paragraph of 35 U.S.C. 112. Accordingly, applicants respectfully request that the Examiners reconsider their stated position and withdraw this ground of rejection against the presently pending claims.

The Rejection Under 35 U.S.C. 102(b)

The Examiners have rejected claims 11-15 under 35 U.S.C. 102(b) as anticipated by the Blecha *et al.* publication [International Publication No. WO 96/32129]. Applicants note also that this PCT printed publication is identical to and claims the priority of U. S. Patent No. 5,830,993 - a prior art patent

which is formally of record and constitutes a substantive part of the prosecution file history for this application.

The Examiners' view is that the Blecha *et al.* publication teaches that native PR-39 and its variants (such as the PR-14 and PR-19 analogs) inhibit leukocyte superoxide anion production; attract leukocytes; and are medicaments that fight infection at a wound site. On this basis, the Examiners then state that "...Blecha *et al.* teach the same truncated PR-39 peptides (e.g., PR-14 and PR-19) as the oligopeptides cited in claims 12, 13 or 14, and the peptides having the same amino acid sequences would be expected to have the same property and function, thus the function of inhibiting proteasome-mediated degradation would be expected for PR-14 and PR-19, even though the cite function is not indicated in the reference." The Examiners' reasoning is thus based solely and exclusively upon the legal doctrine of "inherency"; and the Examiners have concluded that the claims of the present application are "inherently anticipated" by the disclosure of the Blecha *et al.* reference.

In response, applicants respectfully submit and maintain that the Examiners are legally in error as regards the propriety of their using the inherency doctrine with respect to the issue of anticipation under 35 U.S.C. 102(b); that the Examiners' stated view and position concerning the sum and substance of the Blecha *et al.* publication is inaccurate and is a factual

fallacy; and that the Examiners' reliance upon the inherency doctrine is based solely upon a speculative theory which does not have an adquate factual basis to support it. Applicants will now demonstrate and evidence each of these points.

A. The Legal Requirements And Evidentiary Demands Of The 'Inherent Anticipation" Doctrine

Applicants respectfully submit and maintain that the Examiners' rationale and position is centered on an erroneous and distorted interpretation of the legal doctrine of inherency. For this reason, a summary review of the legal doctrine of "inherent anticpation" is presented here.

1. The inclusion of the word "discovery" within the statutory language of 35 U.S.C. 100(a) is both noteworthy and important. As recited therein, the term "invention" includes by definition a discovery of the capabilities or functional traits of a item as well as the creation or isolation of an item. It is well established in law and commonly understood that an inventor may discover something that already previously existed. The mere fact that a thing existed, undiscovered, does not of itself render the item "inherently anticipated" [In re Bergstrom, 166 USPQ 256 (CCPA 1970); In re Kratz, 201 USPQ 71 (CCPA 1979); In re Oelrich, 212 USPQ 578 (CCPA 1981)].

2. The legal precedents concerned with the issue of anticipation under 35 U.S.C. 102 primarily deal with application of the law to situations where (i) a single prior art reference teaches all the elements of a product as claimed [In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997)]; and (ii) a single prior art reference does not teach al the claimed elements but the omitted element is recognized as being "inherently" present within the subject matter of the reference [MEHL/Biophile International Corp. v. Migraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Titanium Metals Corp. v. Banner, 227 USPQ 773 (Fed. Cir. 1985)]. It is the latter situation which is legally material in this instance.

3. Where the law of "inherency" is applied to subject matter wherein all the elements of the invention as claimed are not shown in a single prior art reference, the legal requirement and proper standard to be met for anticipation has been set forth by landmark case of Continental Can Co. v. Monsanto Co. [20 USPQ2d 1746 (Fed. Cir. 1991)] as the following :

> "...To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill....
>
> This modest flexibility in the rule that "anticipation" requires that every element of the

> claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges...." [20 USPQ2d at 1269-1270].

4. The basis of "inherency" thus requires a factual determination of whether those aspects of the claimed subject matter that are not directly taught in the single prior art reference - the missing descriptive information - were nonetheless known in the field of the invention by practitioners ordinarily skilled in that technical area [EMI Group North America Inc. v. Cypress Semiconductor Corp., 60 USPQ2d 1423 (Fed. Cir. 2001)]. Inherency, as a legal tool, must therefore supply those aspects of the claimed invention which are missing and absent from the incomplete description in the single prior art reference; and must provide credible facts and evidence that the ordinarily skilled practitioner in the art is at least acquainted with, if not fully cognizant of, the missing descriptive aspects.

This legal foundation - that a person of ordinary skill in the relevant art must acknowledge or be aware that the missing descriptive aspects are present as part of a commonly-available body of knowledge and information in the technical field - is a crucial and essential point of law. Moreover, such factual acknowledgment or common awareness by persons of ordinary skill in the art is critical for establishing and credibly demonstrating that the

missing descriptive subject matter would intrinsically be present for every embodiment defined by the requisite elements and limitations of the claim language [Finnigan Corp. v. ITC, 51 USPQ2d 1001 (Fed. Cir. 1999)].

5. Inherency, however, can not be established either by "probabilities" or "possibilities". The mere hypothesis that an outcome might result from a given set of circumstances is not sufficient [In re Oelrich, 212 USPQ 323 at 326 (CCPA 1981)]. Thus inherency, as a basis for rejection, is available only when the specific element or particular limitation defined in a claim can be identified and supplied by the ordinary skilled practitioner in the technological field from the disclosure of the single prior art reference with substantial certainty.

Accordingly, probabilities and speculation are not a substitute for substantial certainty and are not sufficient in fact or law to invoke or apply the inherency doctrine [In re Chandler, 117 USPQ 361 (CCPA 1985); In re Wertheim, 191 USPQ 90 (CCPA 1976)]. Moreover, in order for a claimed invention to be inherently disclosed, the invention defined and claimed by applicants must be the sole necessary and only reasonable construction to be given to the prior art disclosure; and the all the elements, particular limitations, and results recited by the wording of applicants' claims must

inevitably exist and be revealed by the cited and applied prior art. [In re Robertson, 49 USPQ2d 1949 (Fed. Cir. 1999)].

6. It is also important to note that the legal burden to establish inherency as a basis for rejection lies exclusively upon the Examiners. The Examiners themselves must demonstrate that the prior art reference, directly or indirectly, discloses and provides all the requisite elements and particular limitations defined by the claim, as well as identifies the resulting capabilities, properties, and traits recited by the claim language with substantial certainty.

If, however, the prior art reference, directly and indirectly, does not describe the claimed subject matter with sufficient clarity and detail to establish that the invention as a whole was known in the prior art and that such information would be at least acknowledged by persons of ordinary skill in the field of the invention, then the single reference is legally inadequate and factually insufficient as a basis for an inherent anticipation rejection [Crown Operations Intl. Ltd. v. Solutia Inc., 62 USPQ2d 1917 at 1921 (Fed. Cir. 2002)].

B. The Factual Content Of The Blecha *et al.* Publication

In conducting this review of the facts disclosed within this prior art reference, applicants will point out what the disclosure of the Blecha *et al.* Printed publication is; what constitutes the means and manner in which the Blecha *et al.* invention is functional and operative; and what are the explicitly imposed limitations and restrictions of the Blecha *et al.* invention as revealed within the single prior art reference itself.

The Examiners' attention is directed particularly to these facts and points of information as the best evidence and proof of what descriptive information is missing from the Blecha *et al.* publication and what descriptive aspects remain completely unknown to the ordinarily skilled practitioner in this technical field.

1. The Blecha *et al.* publication explicitly discloses an attempt to synthesize peptide compositions of varying size and amino acid residue formulation in order to identify those peptide variants which are demonstrably biologically active, anti-microbial in effect, and can be used to inhibit microbial growth and microbial infections [Page 1, lines 7-30]. Blecha *et al.* synthesized a range of differently formulated peptide variant sequences, all of which were loosely based on amino acid sequence fractions present within the 39 amino acid residue length of the native PR-39 peptide - a conventionally known peptide which was previously isolated from wound

fluid and was shown to be biologically active for the induction of syndecan expression in mesenchymal cells [Page 1, lines 34-35; Page 2, lines 1-14].

2. The Blecha *et al.* variant peptides are shorter-length compounds in comparison to the known structure of native PR-39 peptide; but are experimental formulations which were individually tested and empirically evaluated by Blecha *et al.* to determine which variant sequences would retain and demonstrate the well-established anti-microbial properties of the native PR-39 peptide. The experimental testing as conducted by Blecha *et al.* then revealed whether or not the variant peptide formulations had any capacity for the active killing of microorganisms and/or the active suppression of microbial multiplication and/or growth [Page 3, lines 9-20].

3. The Blecha *et al.* publication sets forth the experimental test model; and discloses the use of a series of in-vitro assays to determine empirically which - if any - of the peptide variants might possess and demonstrate the anti-microbial activity of the native PR-39 peptide structure. The empirical assays employed for anti-microbial testing purposes included: the gel-overlay assay, the lawn-spotting assay, the minimal inhibitory concentration test, the measurement of post antibiotic effects, the susceptibility of neutrophil phagocytosis, the regulation of neutrophil

superoxide anion production, neutrophil chemotaxis capability, and the influence on intestinal epithelial cells [Page 6, lines 16-34; Page 7, lines 1-34; Page 8, lines 1-21].

4. The Blecha *et al.* disclosure then states that six variant peptide structures based on the original PR-39 peptide were experimentally synthesized and empirically tested. The amino acid residue formulation of each variant peptide which was experimentally evaluated is shown by Fig. 1 [Page 5, lines 31-35; Page 6, lines 1-15].

Clearly, each of these six variant Blecha *et al.* peptides was of a different length and each variant had an individual amino acid residue formulation. Of these six experimental formulations, only three variant peptides had an amino acid residue sequence which began with the amino acid residues found at the N-terminal end of the native PR-39 molecule, but were synthesized as shorter length peptide structures. These three shorter-length structures are the PR-14, PR-19 and PR-26 peptide variants.

In comparison, the other three synthesized variants were: PR-15, a fifteen residue length peptide structure constituting a fraction of the amino acid residues found at the COOH-terminal end of the native PR-39 peptide molecule; PR-16, a peptide sequence containing only the sixteen amino acid residue to be found at position nos. 11-26 in the native PR-39 peptide

structure; and PR-23, a peptide sequence of twenty three residue length and having only amino acid residues to be found at position nos. 4-26 in the native PR-39 peptide. Thus, as a visual inspection of SEQ ID NOS: 6, 5 and 3 respectively in the publication shows, none of the PR-15, PR-16 or PR-23 peptide structures contained an N-terminus sequence beginning with the amino acid resides Arg-Arg-Arg.

5. The Blecha *et al.* publication also presents the empirical results as to whether or not any of the six peptide variants had retained and demonstrated the desired anti-microbial biological activity of the native PR-39 peptide. Blecha *et al.* overtly state that among the three variant peptides whose formulations began with the amino acid residues found at the N-terminal end of the native PR-39 molecule, the PR-14 and the PR-19 variant peptides in particular failed to retain and failed to show any anti-microbial activity whatsoever [Page 15, lines 27-29]. Equally important, Blecha *et al.* observed and reported that, among the six variant peptides synthesized and experimentally tested, only the PR-26 peptide structure demonstrated any anti-microbial activity similar to that of the native PR-39 peptide [Page 12, lines 18-35; Page 13, lines 1-47].

As emphatically stated therein, the laboratory experiments and resulting empirical data presented within the Blecha *et al.* publication reveal

that only the PR-26 peptide variant alone had any functional biological activity; that only the PR-26 peptide variant empirically showed the required anti-microbial killing properties using the in-vitro assays; and that none of the other five synthesized variant peptide structures had any demonstrable biological activity whatsoever.

6. The disclosure of the Blecha *et al.* publication also explicitly states in detail what the direct teachings and overtly-given conclusions for the experimental tests and empirical results. These are explicitly stated at page 12, lines 30-35 and page 13, lines 1-4 of the publication and are summarized as follows:

(a) The COOH-terminus of the PR-39 structure does not contribute to antibacterial activity;

(b) The N-terminus of the PR-39 structure is not sufficient for antibacterial activity;

(c) The PR-26 peptide containing residue Nos. 1-26 of the original PR-39 structure is the antibacterial domain; and

(d) A particular secondary peptide structure conformation is required to exist and be present, as shown by both the PR-26 peptide and the original PR-39 original peptide, in order that the desired antibacterial activity exist.

7. The Blecha *et al.* publication explicitly and repeatedly states that only one variant peptide structure is demonstrably biologically active and is functional for the intended goal and stated purpose of anti-microbial activity, the PR-26 peptide variant. Of all six variant peptides synthesized and experimentally tested, only the PR-26 peptide variant is said to be suitable and useful via its demonstrated antibacterial properties [Page 13, lines 5-25]. The remaining five variant peptide structures, having no biological activity, are deemed to be of no technical consequence nor have any scientific value whatsoever.

C. The Failure Of The Blecha *et al.* Publication To Teach The Requisite Elements And Limitations Of Applicants' Claimed Invention, Directly Or Indirectly

As shown above, the Blecha *et al.* publication discloses only a very few facts, and these are of little relevance or import with respect to applicant's claimed invention. Applicants therefore direct the Examiners' attention to the following points.

(a) The sole criteria of use for the described Blecha *et al.* peptide variants are exclusively as anti-microbial agents. No other activity, property, or characteristic is revealed or suggested.

(b) Only one synthesized peptide variant of 26 amino acid residue length was empirically found to be biochemically active for its intended purpose. All the other Blecha *et al.* synthesized peptide variants shorter than 26 amino acid residues in length had no anti-microbial activity and thus had neither biological activity nor any functional use as such.

(c) The presence of an antibacterial domain as a distinct moiety is necessary and required as part of the peptide structure in order for the requisite antibacterial activity to exist within the peptide; and, according to Blecha *et al.*, only the PR-26 peptide variant provides the requisite antibacterial domain within its structure in an active form comparable to that present in the native PR-39 peptide.

(d) The mechanism for anti-microbial biological activity is specified by Blecha *et al.;* and is a structural requirement which must be present in order that any short-length peptide be active and functional for its intended purpose, a demonstrable anti-microbial activity. Thus, the interaction and effect of a peptide variant having the requisite anti-microbial domain as part of its structure is an essential and necessary part of the variant peptide's formulation; and any variant peptide formulation of any size which does not include the required anti-microbial domain within its structure cannot provide any biological activity and is not functional for the Blecha *et al.* stated goal - the killing of microbes and the inhibition of microbial growth and infections.

For these reasons, each of the other five synthesized peptide variants, and the PR-14 and PR-19 variant peptides in particular, are abject failures because they have no biological function or demonstrable utility.

(e) The six variant peptides synthesized by Blecha *et al.* are merely laboratory test models and analytical tools employed as workpieces in a prepared experimental program to identify what constitutes and where the anti-microbial domain is to be found in the native PR-39 peptide structure. No interest or value is afforded to any of the six peptide variants - unless and until the distinct capability of anti-microbial killing activity has been empirically shown to exist.

(f) For each of the five different peptide variants (and the PR-14 and PR-19 structures in particular) which empirically failed to show any anti-microbial activity, the consequence of their failure and their resulting, commonly-shared, present status is as follows:

i. Each failed variant peptide sequence synthesized by Blecha *et al.* is and remains merely a scientific curiosity having no scientific or technical value other than bare existence;

ii. Each failed variant peptide sequence synthesized by Blecha *et al.* is and remains merely a laboratory model composition and analytical tool suitable only as a test workpiece in future research experiments; and

iii. Each failed variant peptide sequence synthesized by Blecha *et al.* is and remains a substance without any known utility due to the absence of having any conventionally recognized or empirically demonstrable biological activity.

All of these facts and points of information are explicit, direct and unrelenting outcomes for the Blecha *et al.* peptide variants as a class of compositions generally. It will be recognized and appreciated also that there are no facts, no information, and no suggestions disclosed by the Blecha *et al.* reference which teach the requisite elements and particular limitations of applicants' claimed invention, directly or indirectly.

D. The Prejudicial Errors Made By The Examiners

It appears that the Examiners refuse to recognize that the Blecha *et al.* publication is markedly different and radically remote from applicants' claimed invention; and the Examiners continue to deny that the Blecha *et al.* disclosure blatantly fails to teach the requisite elements and limitations recited by applicants' claimed invention.

Applicants therefore now provide the Examiners with some examples of the many explicit differences and marked distinctions of the Blecha *et al.* disclosure in comparison to applicants' claimed subject matter.

(1) The Blecha *et al.* reference makes an absolute requirement that any synthesized variant peptide structure must demonstrate potent anti-microbial properties and effects as exhibited by the original PR-39 peptide. In contradistinction, applicant's claimed invention is not concerned with or directed to anti-microbial properties.

(2) Blecha *et al.* reference states that no set of characteristics, traits or properties is of any value or is of any interest - except for a demonstrably potent and empirically proven antibacterial activity. Distinctively different is applicant's claimed invention defining a class of compositions able to cause a selective inhibition of proteasome-mediated degradation.

(3) The Blecha *et al.* reference experimentally proves and expressly concludes that of the six variant peptides synthesized and empirically evaluated, only the PR-26 peptide structure - having 26 amino acid residues in sequence - was empirically found to include the antibacterial domain of the native PR-39 peptide, and was biologically active to demonstrate the intended goal and purpose of anti-microbial activity. In comparison, applicant's claimed invention encompasses short-length peptides, all of which must be less than 26 amino acid residues in size, but none of which have the antibacterial domain of the native PR-39 peptide. The present invention also provides several preferred embodiments, each of which is considerably less than 19 amino acid residues in length.

(4) The Blecha *et al.* reference explicitly concludes that no peptide structure synthesized by them regardless of formulation and that no shorter-length peptide variant less than 26 amino acid residues in size is either biologically active or functional for any purpose. In contradistinction, applicant's claimed invention recites and requires an unique pharmacological activity and distinctly different utility - a selective inhibition of proteasome mediated degradation - for each of the different short-length peptide embodiments in the defined class of compounds, all of which are less than 26 amino acid residues in size.

(5) The Blecha *et al.* publication discloses that six short length peptide variants less than 39 amino acid residues in length were synthesized; and that the Blecha *et al.* peptide variants were used as laboratory test models and experimental analytical tools. This is particularly true for those variant peptide formulations less than 26 amino acid residues in length - especially when these variants yielded only negative results and were shown to be abject failures empirically. The failed variant peptides thus bear no direct relationship to the operative and functional combination of elements and limitations defined by applicants' claimed invention.

(6) No failed variant peptide structure synthesized by Blecha *et al.* and no negative experimental data for the failed peptide variants disclosed by the Blecha *et al.* publication can possibly serve as a factual and credible

basis for inferring or suggesting a uniquely positive new result, or a positively identified operative formulation, or a positively recited and previously unknown pharmacological capability - such as is provided by applicants' claimed invention. Clearly, the negative data and results disclosed by Blecha *et al.* emphatically discourage the ordinarily skilled person working in this technical field from using any of the failed variant peptides for any purpose; overtly suggest that any future development flowing from the reported negative data is unlikely to be productive; and expressly indicate that the failed variant peptides are likely to be functionally inoperative and useless for any biological purpose. The Blecha *et al.* disclosure thus teaches and directs the reader away from even the idea that any short-length variant peptide which is an analog of native PR-39 peptide could possibly provide the singular pharmacological capability of being able to cause a selective inhibition of proteasome-mediated degradation in-situ.

Accordingly, it is applicants' view and position that the Examiners' use of the inherency doctrine and their reliance upon "inherent anticipation" as a basis for rejection fails to meet the necessary minimal factual requirements because of the glaring factual deficiencies and the absence of essential descriptive subject matter within the Blecha *et al.* reference. Moreover, because the disclosure of the Blecha *et al.* reference is so blatantly deficient in essential descriptive information, applicants maintain that the rationale

employed by the Examiners as the underlying basis for rejection is factually non-existent, is purely speculative, and is without substantive evidentiary foundation or support as such.

Under these circumstances, the inherency doctrine and "inherent anticipation" may not be properly employed as a legal basis for rejection of the claims. Applicants' position is amply demonstrated and fully supported by the absence of relevant supporting facts, pertinent information, useful knowledge, or data within the single cited and applied reference, the Blecha *et al.* publication.

Applicants' also note that, as a matter of law, the underlying basis of "inherency" requires a factual determination of whether those aspects of applicants' claimed subject matter that do not exist in and are not directly taught by the Blecha *et al.* reference - *i.e.,* the missing essential descriptive information - were nonetheless known in the field of the invention by practitioners ordinarily skilled in that technical area. Thus, to employ "inherent anticipation" as the legal basis for rejection, the Examiners must first supply those missing descriptive aspects of applicants' claimed invention which are absent from the incomplete disclosure of the Blecha *et al.* publication; and the Examiners must then also provide credible facts and probative evidence that the ordinarily skilled practitioner in the art is at least acquainted with, if not fully cognizant of, the missing descriptive aspects

which pertain to and bear upon applicants' claimed subject matter as a whole.

The Examiners, however, have failed to provide any extrinsic information, data and knowledge at all - a legal burden which is their sole and exclusive obligation; and such extrinsic knowledge must be presented by the Examiners to support their rejection basis because the cited and applied Blecha *et al.* reference is so utterly lacking and clearly deficient in the requisite elements and particular limitations recited by applicants' claimed invention.

The extrinsic evidence yet to be provided by the Examiners must provide the essential missing descriptive matter to serve as a foundation; and be sufficient in factual content that a person of ordinary skill in the relevant art would acknowledge or would be aware that the missing descriptive aspects which are absent and omitted from the Blecha *et al.* disclosure are indeed present as part of a commonly-available body of knowledge and information in the technical field. Moreover, such factual acknowledgment or common awareness by persons of ordinary skill in the art is critical for establishing and credibly demonstrating that the missing descriptive subject matter would intrinsically be present in every embodiment defined by the requisite elements and limitations of applicants' claim language.

For the reasons presented above, applicants thus find the Examiners' stated views and conclusions to be factually inaccurate and legally erroneous with respect to applicants' claimed invention. The Examiners' stated reasons for using the "inherency doctrine" and for employing "inherent anticipation" as a rejection basis have been shown to be unsupportable, unjustified and erroneous in their entirety.

It is equally evident that, in an attempt to impose their stated views and positions, the Examiners have acted subjectively, wrongly and prejudicially. The Examiners have ignored the sum, substance and value of the few relevant facts disclosed by the Blecha *et al.* publication. In a similar manner, the Examiners have unfortunately disregarded and evaded from the controlling authority of long-established legal standards, which deny and refute as a matter of law the Examiners' expressed reasons and views regarding "inherent anticipation". Ample evidence demonstrating each of these prejudicial factual and legal errors has been presented in detail herein.

Accordingly, for all these reasons, applicants respectfully request that the Examiners reconsider their sated position and withdraw this ground of rejection against the presently pending claims.

Applicants have addressed each basis of rejection stated in the instant Official Action forthrightly and objectively. In applicants' view, each issue or

controversy has been evaluated, acted upon and resolved completely. For these reasons, applicants respectfully submit and affirm that amended claims 11-15 now pending are therefore now allowable.

In view of the above discussion and detailed review, applicants believe that this case is now in condition for allowance and reconsideration is respectfully requested. The Examiners are invited to call applicants' undersigned attorney should they feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

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